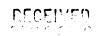
Hoechst Celanese



Department of Environmental, Health & Safety Affairs (DEHSA) SS FEE 22 PM 2: 57

A

ORIGINAL

Hoechst Celanese Corporation Route 202-206 PO Box 2500 Somerville. NJ 08876-1258 908 231 2000 Telex 833 449 Fax 908 231 4554

February 13, 1995 RAJ-020-95

Attn: TSCA Section 8(e) Coordinator Document Processing Center (TS-790) U.S. Environmental Protection Agency 401 M Street, S.W. Washington, D.C. 20460

Contains no CBI

Dear Sir or Madam:

In accordance with the reporting requirements of TSCA Section 8(e), Hoechst Celanese Corporation hereby submits the preliminary results of an acute oral toxicity study in rats for α -aminoethylphenol, ethoxylate (CAS no. unknown). The draft of the study report is attached.

In this study, central nervous system effects were observed at two dose levels: 5000 and 2000 mg/kg. At the 5000 mg dose, convulsions or tremors were observed in 3 of the 10 animals within 3-4 hours of administration; these 3 animals all died on day-0. At the 2000 mg dose, tremors were observed in 1 animal which died on day-1.

The use of the chemical is limited to R&D activities.

This submission contains no confidential business information.

If any further information is required, do not hesitate to contact Dr. Richard A. Jourdenais, Manager, Product Stewardship at 908-231-3746.

Sincerely,

Susan Engelman

Vice President, Environmental, Health &

Safety Affairs

RAJ/mcs Attachment

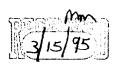
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8EHQ-95-13341

INIT 02/22/95

88950000138



UBTL, INC. 520 WAKARA WAY SALT LAKE CITY, UT 84108

DRAFT REPORT

ACUTE ORAL TOXICITY STUDY
IN RATS ADMINISTERED
TEST ARTICLE C-01952
p-ALPHA-AMINOETHYLPHENOL ETHOXYLATE (EAEP)

UBTL STUDY 67098 PROTOCOL AOOECDL-010

Contain in CBI

PREPARED FOR

HOECHST CELANESE CORPORATION ROUTE 202/206, P.O. BOX 2500 SOMERVILLE, NJ 08876-1258 (908) 231-2813

UBTL, INC. 520 WAKARA WAY SALT LAKE CITY, UT 84108

REPORT APPROVAL PAGE

J. Robert Mattinson, B.S. Study Director	Date
· · · · · · · · · · · · · · · · · · ·	 Date
R. Wayne Ball, Ph.D., D.A.B.T. Associate Director of Toxicology	Date

UBTL, INC. 520 WAKARA WAY SALT LAKE CITY, UT 84108

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

The portions of this study conducted at UBTL were in accordance with the OECD regulations for Good Laboratory Practice with any exceptions as listed in the Data Integrity Statement found in Appendix C.

Evaluations related to the chemical composition, purity, strength and stability of the test article or the concentration, uniformity and stability of any mixtures used were the responsibility of the Sponsor. Therefore, these evaluations were not performed by the testing facility.

J. Robert Mattinson, B.S.	Date
Study Director	

ACUTE ORAL TOXICITY STUDY IN RATS ADMINISTERED TEST ARTICLE C-01952 p-ALPHA-AMINOETHYLPHENOL ETHOXYLATE (EAEP)

ABSTRACT

Undiluted test article C-01952 was administered orally to five male and five female animals at 5.0 g/kg. As significant mortality was observed, an additional dose level (2.0 g/kg) was initiated using five males and five females in order to further clarify and define the mortality and significant clinical signs.

The oral toxicity test resulted in 80% mortality in the 5.0 g/kg dose group and 10% mortality in the 2.0 g/kg dose group. Two animals in the 5.0 g/kg dose group died prior to any observations being performed on Day 0. Three animals of the 5.0 g/kg dose group and one animal of the 2.0 g/kg dose group exhibited tremors and/or convulsions on Day 0 and were found dead on Day 1. Abnormal respiration (wheezing and/or labored breathing) was exhibited by 4 animals in the 5.0 g/kg dose group and one animal in the 2.0 g/kg dose group of which four died and one (5.0 g/kg) returned to normal by study Day 1. There were no target organs which were identified as being clearly related to test article administration. Based on the results of this assay, the acute oral LD50 for test article C-01952 is considered to be greater than 2.0 g/kg and less than 5.0 g/kg.

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UBTL STUDY 67098 PROTOCOL AOOECDL-010

OBJECTIVE

The objective of this study was to evaluate the acute oral toxicity of the test article when administered as a single dose by gavage to rats.

PROCEDURE

Protocol AOOECDL-010 (UBTL Study 67098) was followed. This study is consistent with the OECD guidelines for testing of chemicals and the EPA (TSCA) guidelines as published in the Code of Federal Regulations (40 CFR, Part 798.1175).

Five male and five female Sprague Dawley rats for each dose level (5.0 g/kg and 2.0 g/kg) were randomly selected by a computer randomization program. Animals were selected to test based on their prefasted body weights. The animals were fasted the night immediately prior to dosing.

Undiluted test article C-01952 was administered orally to five male and five female animals at a dose level of 5.0 g/kg. The mortality was 80%; therefore, an additional dose level using five male and five female rats was performed at 2.0 g/kg. Individual dosing volumes were adjusted based upon the density of the test article and the animal's fasted body weight.

Observations were made hourly for the first 4 hours immediately after dosing and twice daily (a.m. and p.m.) for the next 13 days - a total of 14 days of observation. Observations were made in accordance with UBTL SOP.

Animal body weights were recorded at the following intervals:

-within 48 hours of receipt -the day before dosing (prefasted)* -the day of dosing (fasted)* -week 1* -termination/death*

*Data presented in Table 3

Animals dying on test or terminated at the end of the study underwent a postmortem examination. All tissues with identified lesions (from all dose groups) were collected and preserved in 10% neutral buffered formalin for possible histopathologic examination. However, the lesions were considered to be incidental and were discarded upon consultation with the sponsor.

The Test System Specifications, Test Article Description, Data Integrity Statement, Study Personnel and Quality Assurance Statement are found in Appendices A. B. C. D and E. respectively.

UBTL STUDY 67098 PROTOCOL AOOECDL-010

STUDY DATES

Study Start Date (Date protocol is signed by the Study Director):

02-Nov-94

Experimental Start Date (First day of dosing):

09-Nov-94

Experimental Completion Date: (last day data are collected from study):

30-Nov-94

Study Completion Date (Date final report is signed by the Study Director):

Refer to the signature page

TRANSFORMATIONS, CALCULATIONS OR OPERATIONS PERFORMED ON DATA

Mean and standard deviation values were calculated for the body weight data.

LOCATION OF ALL RAW DATA:

The original raw data, protocol and protocol amendment and final report for this study are maintained in the UBTL archives under Study 67098.

RESULTS:

Mortality:

The following mortality was observed in the dose groups:

DOSAGE	MALE	FEMALE
5.0 g/kg	60% (3/5)	100% (5/5)
2.0 g/kg	20% (1/5)	0% (0/5)

All animal deaths occurred within one day of test article administration.

The mortality data are summarized in Table 1.

In-Life Observations

Two animals of the 5.0 g/kg dose group died prior to any observations being performed on Day 0.

Nine animals (1 male rat in the 5.0 g/kg dose group; 3 males and 5 females in the 2.0 g/kg dose group) appeared normal throughout the study period.

Remaining animals of both dose groups exhibited one or more of the following observations during the study period: oral discharge, stained coat, abnormal stools, abnormal respiration (wheezing and/or labored breathing), tremors, convulsions and/or lethargy.

All animals which survived the 14-day study period, appeared normal by study Day 1.

In-Life observations are summarized in Table 2.

UBTL STUDY 67098 PROTOCOL AOOECDL-010

Body Weight

All surviving test animals had gained weight by the end of their respective study periods.

Body weight data are summarized in Table 3.

Necropsy:

Animals that survived the study period were euthanized by CO₂. All animals at the conclusion of the study and those that died on study were subjected to a postmortem examination.

The eleven surviving animals (two in the 5.0 g/kg dose group and nine in the 2.0 g/kg dose group) did not exhibit any visible lesions at necropsy.

The animals which died on test exhibited one or more of the following observations at necropsy: oral discharge; stained coat; gastrointestinal tract fluid and/or gas filled; enlarged cervical lymph nodes and/or discoloration of the lungs, liver and/or heart.

Necropsy data are summarized in Table 4.

CONCLUSION:

The oral toxicity test resulted in 80% mortality in the 5.0 g/kg dose group and 10% mortality in the 2.0 g/kg dose group. Two animals in the 5.0 g/kg dose group died prior to any observations being performed on Day 0. Three animals of the 5.0 g/kg dose group and one animal of the 2.0 g/kg dose group exhibited tremors and/or convulsions on Day 0 and were found dead on Day 1. Abnormal respiration (wheezing and/or labored breathing) was exhibited by 4 animals in the 5.0 g/kg dose group and one animal in the 2.0 g/kg dose group of which four died and one (5.0 g/kg) returned to normal by study Day 1. There were no target organs which were identified as being clearly related to test article administration. Based on the results of this assay, the acute oral LD50 for test article C-01952 is considered to be greater than 2.0 g/kg and less than 5.0 g/kg.

TABLE 1

MORTALITY DATA SUMMARY

DAY	0	1	2	3	4	5	6	7_	8	9	10	11_	12	13
ANIMALS ALIVE	5	2	2	2	2	2	2	2	2	2	2	2	2	2
ANIMALS DEAD	5	8	8	8	8	8	8	8	8	8	8	8	8	8
PERCENTAGE DEAD	50	80	80	80	80	80	80	80	80	80	80	80	80	80
MALES ALIVE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
MALES DEAD	3	3	3	3	3	3	3	3	3	3	3	3	3	3
PERCENTAGE DEAD	60	60	60	60	60	60	60	60	60	60	60	60	60	60
FEMALES ALIVE	3	0	0	0	0	0	0	0	0	0	0	0	0	0
FEMALES DEAD	2	5	5	5	5	5	5	5	5	5	5	5	5	5
PERCENTAGE DEAD	40	100	100	100	100	100	100	100	100	100	100	100	100	100

TABLE 1
MORTALITY DATA SUMMARY

DAY	0	1	2	3	4	5	6	7	8	9	10	11	12	13
ANIMALS ALIVE	10	9	9	9	9	9	9	9	9	9	9	9	9	9
ANIMALS DEAD	0	1	1	1	1	1	1	1	1	1	1	1	1	1
PERCENTAGE DEAD	0	10	10	10	10	10	10	10	10	10	10	10	10	10
MALES ALIVE	5	4	4	4	4	4	4	4	4	4	4	4	4	4
MALES DEAD	0	1	1	1	1	1	1	1	1	1	1	1	1	1
PERCENTAGE DEAD	0	20	20	20	20	20	20	20	20	20	20	20	20	20
FEMALES ALIVE	5	5	5	5	5	5	5	5	5	5	5	5	5	5
FEMALES DEAD	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PERCENTAGE DEAD	0	0	0	0	0	0	0	0	0	0	0	0	0	0

TABLE 2 IN-LIFE OBSERVATIONS SUMMARY (days following treatment)

•									
OBSERVATION	lhr*	2hr*	3hr*	4hr*	1	2	3	4	5
NORMAL	61/8**	5/8	3/8	22/5	2/2	2/2	2/2	2/2	2/2
ABNORMAL STOOLS	2/8	2/8	0/8	0/5	0/2	0/2	0/2	0/2	0/2
ABNORMAL RESPIRATION ³	0/8	0/8	3/8	3/5	0/2	0/2	0/2	0/2	0/2
ORAL DISCHARGE	1/8	1/8	3/8	4/5	0/2	0/2	0/2	0/2	0/2
TREMORS	0/8	0/8	(2/8)	1/5	0/2	0/2	0/2	0/2	0/2
CONVULSIONS	0/8	0/8	0/8	(2/5)	0/2	0/2	0/2	0/2	0/2
LETHARGIC	0/8	0/8	0/8	1/5_	0/2	0/2	0/2_	0/2	0/2
OBSERVATION	6	7	8	9	10_	11	12	13	
NORMAL	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	
ABNORMAL STOOLS	0/2	0/2	0/2	0/2	0/2	0/2	0/2	0/2	
ABNORMAL RESPIRATION ³	0/2	0/2	0/2	0/2	0/2	0/2	0/2	0/2	
ORAL DISCHARGE	0/2	0/2	0/2	0/2	0/2	0/2	0/2	0/2	
TREMORS	0/2	0/2	0/2	0/2	0/2	0/2	0/2	0/2	
CONVULSIONS	0/2	0/2	0/2	0/2	0/2	0/2	0/2	0/2	
LETHARGIC	0/2	0/2	0/2	0/2	0/2	0/2	0/2	0/2	

Day of dosing, values given in hours

Number of animals with a given observation (A.M. and/or P.M.)/number of animals alive after the last observation of the hour or day

Two animals died prior to 1 hour observation 1

Three animals were found dead following 4 hour observation but prior to the 2 end of the day

Respiration observations include wheezing and/or labored breathing 3

TABLE 2 IN-LIFE OBSERVATIONS SUMMARY (days following treatment)

OBSERVATION	1hr*	2hr*	3hr*	4hr*	1	2	3	4	5
NORMAL	10/10**	*9/10	9/10	8/10	9/9	9/9	9/9	9/9	9/9
ABNORMAL RESPIRATION ¹	0/10	0/10	1/10	1/10	1/9	0/9	0/9	0/9	0/9
ORAL DISCHARGE	0/10	1/10	1/10	1/10	1/9	0/9	0/9	0/9	0/9
TREMORS	0/10	1/10	1/10	1/10	0/9	0/9	0/9	0/9	0/9
STAINED COAT	0/10	0/10	0/10	0/10	1/9	0/9	0/9	0/9	0/9
LETHARGIC	0/10	1/10	1/10	2/10	1/9	0/9	0/9	0/9	0/9
OBSERVATION	6	7	8	9	10	11_	12	13	
NORMAL	9/9	9/9	9/9	9/9	9/9	9/9	9/9	9/9	
ABNORMAL RESPIRATION ¹	0/9	0/9	0/9	0/9	0/9	0/9	0/9	0/9	
ORAL DISCHARGE	0/9	0/9	0/9	0/9	0/9	0/9	0/9	0/9	
TREMORS	0/9	0/9	0/9	0/9	0/9	0/9	0/9	0/9	
STAINED COAT	0/9	0/9	0/9	.0/9	0/9	0/9	0/9	0/9	
LETHARGIC	0/9	0/9	0/9	0/9	0/9	0/9	0/9	0/9	_

Day of dosing, values given in hours Number of animals with a given observation (A.M. and/or P.M.)/number of animals alive after the last observation of the hour or day

Labored breathing

TABLE 3

BODY WEIGHT DATA SUMMARY (weight in grams)

Animal	F	re-Fasted	Fasted	Week 1	Terminal/	Weight
Number	Scx	Weight	Weight	Weight	Dead Weight	Change
235704	М	278	257	**(0)	**	**
235721	М	272	242	**(0)	**	**
235723	М	282	259	317	361	7 5
235724	М	283	262	**(0)	**	**
235728	М	271	246	298	332	61
235735	F	234	211	**(0)	**	**
235736	F	230	212	**(1)	**	**
235750	F	220	201	**(1)	**	**
235758	F	231	214	**(0)	**	**
235759	F	223	208	**(1)	**	**
Male Mea	n±SD	277 ± 6	253 ± 9	308 ± 13*	347 ± 21*	68 ± 10*
Female M	ean±SD	228 ± 6	209 ± 5	**	**	**

⁽⁾ Study Day of Death - Indicated only when animal dies on study.

^{*} Mean and standard deviation values do not reflect animals that died before the scheduled weighing points.

^{**} Data does not apply due to animal death

Study Weight Change = (Terminal/Death Weight) - (Pre-fasted Weight)

TABLE 3

BODY WEIGHT DATA SUMMARY (weight in grams)

Animal	F	re-Fasted	Fasted	Week 1	Terminal/	Weight
Number	Sex	Weight	Weight	Weight	Dead Weight	Change
235701	M	303	276	350	374	7 1
235705	M	335	303	378	404	69
235710	М	333	303	**(0)	**	**
235715	M	310	280	344	370	60
235719	M	299	271	336	361	62
235742	F	244	222	271	278	3 4
235747	F	257	235	281	280	23
235749	F	239	215	250	269	3 0
235756	F	234	204	259	268	3 4
235757	F	250	227	272	269	19
Male Mean	n±SD	316 ± 17	287 ± 15	352 ± 18*	377 ± 19*	66 ± 5*
Female M	ean±SD	245 ± 9	221 ± 12	267 ± 12	273 ± 6	28 ± 7

^() Study Day of Death - Indicated only when animal dies on study.

Study Weight Change = (Terminal/Death Weight) - (Pre-fasted Weight)

^{*} Mean and standard deviation values do not reflect animals that died before the scheduled weighing points

^{**} Data does not apply due to animal death

TABLE 4

GROSS NECROPSY SUMMARY (TS = Terminal Sacrifice)

Animal Number	Study Day Of Death	Sex	Gross Necropsy Observations
235704	0	М	Cervical Lymph Nodes: Enlarged approximately 2-3 times normal size Lungs: Dark red in color Liver: Dark red in color Stomach: Fluid filled
235721	0	M	Heart: Dark red (almost black) Liver: Dark red all lobes Lungs: Dark red all lobes Stomach: Fluid filled
235723	TS	M	No Visible Lesions
235724	0	M	External Examination: Clear oral discharge Stomach: Yellow fluid filled Lungs: Left apical lobe dark red, multiple spots approximately 2mm in diameter; mottling Gastrointestinal Tract: Yellow fluid filled
235728	TS	M	No Visible Lesions
235735	0	F	External Examination: Clear oral discharge Lungs: Brown spots with red mottling on all lobes Stomach: Fluid and gas filled
235736	1	F	External Examination: Clear oral discharge Stomach: Fluid filled
235750	1	F	Exiternal Examination: Clear oral discharge Stomach: Fluid filled
235758	0	F	Cervical Lymph Nodes: Enlarged approximately 2 times normal size Stomach: Fluid filled
235759	1	F	External Examination: Cleaar oral discharge Stomach: Fluid filled

TABLE 4

GROSS NECROPSY SUMMARY (TS = Terminal Sacrifice)

Animal <u>Number</u>	Study Day Of Death	Sex	Gross Necropsy Observations
235701	TS	M	No Visible Lesions
235705	TS	M	No Visible Lesions
235710	1	М	External Examination: Wet yellow material around mouth; slight yellow staining, anogenital region Stomach: Fluid filled
235715	TS	M	No Visible Lesions
235719	TS	M	No Visible Lesions
235742	TS	F	No Visible Lesions
235747	TS	F	No Visible Lesions
235749	TS	F	No Visible Lesions
235756	TS	F	No Visible Lesions
235757	TS	F	No Visible Lesions

APPENDIX A TEST SYSTEM SPECIFICATIONS

ANIMAL DESCRIPTION (Study Specific)

Species:

Rat

Strain:

Sprague Dawley

Number/Sex:

5.0 g/kg: 5 males and 5 females 2.0 g/kg: 5 males and 5 females

Source:

Healthy animals were obtained from Charles River,

Portage, MI.

Age:

Young Adults

Body Weight Range:

5.0 g/kg: 220-283 grams at pre-fast. 2.0 g/kg: 234-335 grams at pre-fast.

Animal weights fell within 20% of the group mean.

Acclimation Period:

7 days for animals in the 5.0 g/kg dose group and 14

days for animals in the 2.0 g/kg dose group.

Animal Identification:

Each animal was assigned a unique number. This number was permanently indicated on each animal

with an ear tag.

Method of Euthanasia:

Euthanasia was accomplished using carbon dioxide

HUSBANDRY DESCRIPTION (Protocol Specific)

Room:

Animals were housed separately from any other

species.

Caging:

Individually housed in stainless steel, wire mesh bottom

cages.

Climate:

Animal room air was 100% fresh with not less than 10

air changes per hour.

Temperature:

64°F - 79°F

Humidity:

30% - 70% relative humidity

(per OECD)

Light:

12/12 hour, light/dark cycle

Monitoring:

Animal room temperature and humidity were monitored daily with a minimum/maximum thermometer. Humidity was recorded daily.

. **UBTL STUDY 67098** PROTOCOL AOOECDL-010

APPENDIX A TEST SYSTEM SPECIFICATIONS (Continued)

Maintenance:

Animal rooms were cleaned at least three times per

week.

Fced:

Fresh certified Agway rodent feed was provided ad libitum, except feed was withheld the night prior to

dosing.

Water:

Fresh potable water was provided ad libitum.

APPENDIX B

TEST ARTICLE DESCRIPTION (as provided by Sponsor)

Test Article Code

Number:

C-01952

Chemical Name:

p-Alpha-Aminoethylphenol Ethoxylate (EAEP)

SN Number:

SN-11357

Physical Description:

Slight yellow, viscous liquid

Density¹:

1.1279 g/ml

 pH^2 :

6

Stability:

Stable at room temperature

Solubility:

Soluble in water

Storage conditions:

Keep away from heat, sparks and flames.

Handling Precautions:

Avoid contact with skin and eyes. Wear NIOSH-

approved respirator.

Characteristics:

Characterization of each lot or batch before its use in the study, documentation of synthesis, determination of solubility (when relevant) and stability both before the experimental starting date or concurrently were

the responsibility of the sponsor.

Reserve Sample:

A reserve sample of each batch and/or lot of test article

was collected prior to use. The reserve sample shall be

maintained in archives.

As determined by UBTL according to SOP TA-040

As determined by UBTL using pHydrion paper (0-13)

APPENDIX C

DATA INTEGRITY STATEMENT

Deviations

Postmortem weights on three animals which were found on study Day 1 were not collected.

The a.m. and p.m. observations for the two surviving animals dosed at 5.0 g/kg on one day of the study period were not performed 4 hours apart as per UBTL SOP.

Integrity Conclusion

The Study Director does not believe that the deviations listed above have adversely affected the quality or integrity of the data in this study.

APPENDIX D

STUDY PERSONNEL

Study Director:	1.	J. Robert Mattinson, B.S.
Other Scientists, Professionals or Supervisors:	2.	R. Wayne Ball, Ph.D., D.A.B.T., Associate Director of Toxicology
	3.	Sheryl M. Dutson, M.S., Manager of Toxicology
	4.	Amanda Sarwacinski, B.A., Technician
	5.	Athena C. D. Webster, B.S., Technician
	6.	Ada M. Alvarado, Assistant Technician

APPENDIX E

UBTL, INC 520 WAKARA WAY SALT LAKE CITY, UT 84108

QUALITY ASSURANCE STATEMENT

Study:

67098

Protocol:

AOOECDL-010

Study Title:

Acute Oral Toxicity Study in Rats Administered Test Article

C-01952, p-Alpha-Aminoethylphenol Ethoxylate (EAEP)

This study was inspected by the Quality Assurance Unit and the findings of the inspections were reported to the management and to the Study Director on the dates given below.

Phase Inspected	Date Inspected	Date Reported
Protocol Dosing	02 Nov 94 09 Nov 94	02 Nov 94 09 Nov 94
Observations	09 Nov 94	09 Nov 94
Necropsy	23 Nov 94	23 Nov 94
Body Weights	14 Nov 94 16 Nov 94	14 Nov 94 16 Nov 94
Dosing Protocol Amendment	27 Dec 94	27 Dec 94
Data/Draft Report	19 Jan 95	19 Jan 95

Lynn M. Kolhepp, B.S.

Quality Assurance



A. .

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Susan P. Engelman
Vice President
Environmental Health & Safety Affairs
Hoechst Celanese Corporation
Route 202-206
P.O. Box 2500
Somerville, New Jersey 08876-1258

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 2 4 1995

FPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Lenter (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Risk Analysis Branch

Enclosure

13341A



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Triage of 8(e) Submissions

Date sent to triage:	12/14/95		NON	-CAP	САР
Submission number: _	13341	<u>A</u> _	TSC/	A Inventory:	YND
Study type (circle app	ropriate):				
Group 1 - Dick Cleme	ents (1 copy total)			
ECO	AQUATO				
Group 2 - Ernie Falke	e (1 copy total)				
ATOX	SBTOX	SEN	W/NEUR)	
Group 3 - Elizabeth	Margosches (1 c	opy each)			
STOX	стох	EPI	RTOX	GTOX	
STOX/ONCO	CTOX/ONCO	IMMUNO	СҮТО	NEUR	
Other (FATE, EXPO, I	MET, etc.):				
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INFORMATION REQUESTED: FLWP DATE: 6501 NO INFO REQUESTED (TECH) 6503 INFO REQUESTED (VOL ACTIONS) 6504 INFO REQUESTED (VOL ACTIONS) 6504 INFO REQUESTED (REPORTING RATIONALE) 6505 INFO REQUESTED (REPORTING RATIONALE) 6505 INFO REQUESTED (REPORTING RATIONALE) 6605 RATIONALE) 6605 CAP NOTICE	195 CSRAD DATE: 03 15/95 CASA CASA Unknown	EPICLIN	RECIES TOXICOLOGICAL CONCERN: RED HIGH
SEO. A	ONS DATE: OQ (2)	P. F. C. INFORI 01 02 04 0217 01 02 04 0217 01 02 04 0218 01 02 04 0220 01 02 04 0221 01 02 04 0221 01 02 04 0222 01 02 04 0222	YES (DROP/REFER) NO (CONTINUE) REFF.R
CECATS DATA: Submission # 8EHQ- O2 95 - 1334 SEO. A Submission # 8EHQ- O2 95 - 1334 SEO. A SUBMITTER NAME: Hochst Celonese Copperhon	C- ONS 2	INFORMATION TYPE: 1201 ONCO (HUMAN) 0.202 ONCO (HUMAN) 0.203 CELL TRANS (IN VITRO) 0.204 MUTA (IN VITRO) 0.205 MUTA (IN VITRO) 0.206 MUTA (IN VITRO) 0.206 REPRO/IERATO (HUMAN) 0.207 REPRO/TERATO (ANIMAL) 0.210 ACUTE TOX. (HUMAN) 0.211 CHR. TOX. (HUMAN) 0.212 SUB ACUTE TOX. (ANIMAL) 0.213 SUB ACUTE TOX (ANIMAL) 0.214 SUB CHRONIC TOX (ANIMAL) 0.215 CHRONIC TOX (A	TRIAGEDATA NON-CBI INVENTORY YES CAS SR NO IN NAMINI IN NAMINI

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Acute oral toxicity in the rat is of low concern. Sprague-Dawley rats (5/sex/dose) received single doses of 5,000 or 2,000 mg/kg. At 2,000 mg/kg, 1/10 animals died (1M) and at 5,000 mg/kg, 8/10 animals died (3/5 males and 5/5 females). Clinical signs included tremors and/or convulsions (1/10 at 2,000 mg/kg and 3/10 at 5,000 mg/kg), wheezing or labored respiration (1/10 at 2,000 mg/kg and 4/10 at 5,000 mg/kg), oral discharge, and lethargy. Histopathologic changes were seen at 5,000 mg/kg only in the lungs and liver (discolored), stomach (fluid-filled), and cervical lymph nodes (enlarged).